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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,420	08/04/2006	Francois Romagne	INN-136	8346

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
06/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,420	ROMAGNE ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *58-96* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Lack of Unity of Invention

Claims 58-96 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 58-89, drawn to methods of treating a carcinoma or viral infection.

Group II, claim(s) 90-96, drawn to articles of manufacture.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

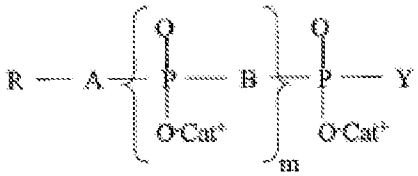
3. WO03/038072 describes the first appearing special technical feature directed to the administration (in vivo, see page 14, line 27) of a combination composition that comprises both a Mycobacterium antigen (see page 5, line 33 and page 14, lines 5-10) and a gamma-delta T-cell stimulator (see page 5, line 13; as well as page 14, lines 5-10, page 5, line 30-35; page 14, lines 26-29 "virally-infected cell", "cancer cell", “melanoma” see page 13, line 26) to treat a virus infection or a carcinoma (melanoma is a specific type of carcinoma (applicant claim 59)) . The prior art anticipates the first appearing invention, thus the claimed inventions do not share a common special technical feature that makes a contribution over the prior art and Lack of unity of invention exists between the claimed inventions.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

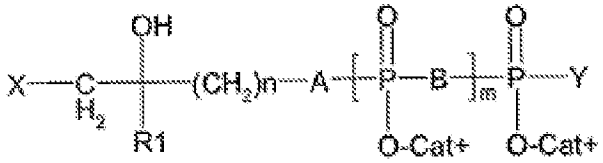
Species I: a Mycobacterium antigen (claims 58, 60-63, 75-79) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 85), together with any gamma-delta stimulatory compound.

Species II: Mycobacterium antigen (claims 64-65) or any one of the immunostimulatory or immunomodulatory compounds listed in (claims 80, 87) together with a compound of formula (I) compounds of formula (I) :



described in pages 44-50

Species III: Mycobacterium antigen (claims 66, 68) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 81, 88) together with a compound of formula (II) described in page 50:

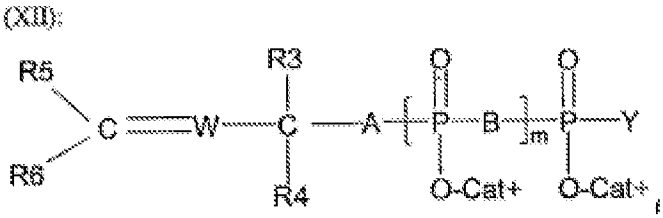


Species IV: Mycobacterium antigen (claims 67, 69) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 88) together with BrHPP (claim 82), a compound of formula (II)

Species V: Mycobacterium antigen (claims 67, 69) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 88) together with CBrHPP (claim 82), a compound of formula (II)

Species VI: Mycobacterium antigen (claims 67, 69) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 88) together with epoxPP (claim 82), a compound of formula (II)

Species VII: Mycobacterium antigen (claims 70, 72) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 83, 89) together with a compound of formula antigen and compounds of formula (XII)

(XII):  described in page 53.

Species VIII: Mycobacterium antigen (claims 71, 73) or any one of the immunostimulatory or immunomodulatory compounds listed in (claim 84, 89) together with HDMAPP, a compound of formula (XII)

Species IX: Mycobacterium antigen (claims 71 73) or any one of the immunostimulatory or immunomodulatory compounds listed in (claims 84,89) together with CHDMAPP, a compound of formula antigen and compounds of formula (XII)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner: See listed species and claims above.

The following claim(s) are generic: claim 74 is generic.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: WO03/038072 describes the first appearing special technical feature directed to the administration (in vivo, see page 14, line 27) of a combination composition that comprises both a Mycobacterium antigen (first species of invention) (see page 5, line 33 and page 14, lines 5-10) and a gamma-delta T-cell stimulator (see page 5, line 13; as well as page 14, lines 5-10, page 5, line 30-35; page 14, lines 26-29 "virally-infected cell", "cancer cell", "melanoma" see page 13, line 26) to treat a virus infection or a carcinoma (melanoma is a specific type of carcinoma (applicant claim 59)) .

7. Additionally, US PG-Pub 2002/0044951 (see claims 1-4 "Bacille Calmette-Guerin adjuvant together with a purified Mycobacterium tuberculosis nonpeptide antigen and a T-cell stimulating compound) discloses a combination composition for stimulation of an immune response against Mycobacterium tuberculosis, but comprises the same components as the claimed article of manufacture, but uses the composition for a different purpose from the first appearing invention of instant claim 58.

The article of manufacture of Group II differs in structures, function and biological effect from that of Group I and the prior art anticipates the first appearing invention, thus the claimed inventions do not share a common special technical feature that makes a contribution over the prior art and Lack of unity of invention exists between the claimed inventions and species of invention.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
May 29, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645